IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of
EDMEADES

Atty. Ref.: 1430-272

Serial No. 09/940,422

Group: 1743

Filed: August 29, 2001

Examiner: Soderquist

For: COMPOUND AND ITS USE

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December 18, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. § 1.55 and in conformance with the procedures of 37 C.F.R. § 1.98, applicants hereby bring to the attention of the examiner documents cited in an opposition filed in the counterpart European patent 963980 corresponding to the parent of the subject application. These documents are listed on the attached modified PTO Form No. 1449.

Included is a document identified as "Analysis Conducted by Agrobiogen on Lamotrigine Tablets". Agrobiogen, one of the opponents, purported to test tablets pertaining to impurity B which is not the subject of the present application. No further information or explanation of this document is available to applicants at this time.

It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

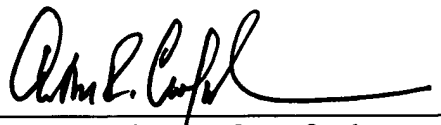
Please return to the undersigned a copy of the attached PTO-1449 with the examiner's initials in the left column [MPEP § 609] with the next communication.

Our check in the amount of $180 is submitted herewith to secure consideration of this filing [see 37 CFR §1.97(c)(2)].

The Commissioner is hereby authorized to charge our Deposit Account No. 14-1140 for any fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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INFORMATION DISCLOSURE CITATION

ATTY. DOCKET NO.	SERIAL NO.
1430-272	09/940,422

APPLICANT

EDMEADES

(Use several sheets if necessary)

FILING DATE	GROUP
August 29, 2001	1743

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		4,108,877	8/1978	Klenk et al			
		4,602,017	7/1986	Sawyer et al			

FOREIGN PATENT DOCUMENTS

		DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
		0 247 892 B1	4/1991	EP				
		0 021 121	6/1983	EP				
		0 059 987	8/1985	EP				
		WO 97/00681	1/1997	PCT				
		WO 96/20934	7/1996	PCT				
		WO 96/17611	6/1996	PCT				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

		PEC Update, February 13, 1995, Pharmacoeconomic Center, Ft. Sam Houston, Texas 78234-5036.
		Dreassi et al, "Quantitative Analysis of Lamotrigine in Plasma ...", Journal of AOAC International, Vol. 79, No. 6, 1996, pages 1277-1280.
		Quaglia et al, "Determination of chlorthalidone and Its Impurities ...", Journal of Chromatography, 436 (1963) 435-439.
		DeAngelis et al, "Quantitation of the Anticonvulsant Cinromide ...", Journal of Chromatography, 221 (1980) 353-360.
		Organic Synthesis, Collective Volume I, being a Revised Edition of Annual Volumes I-IX, pages 146-149, Henry Gilman, Editor in Chief, John Wiley & Sons Publisher, © 1941; ISBN 471 30030 6.
		Organic Synthesis, Collective Volume 2, being a Revised Edition of Annual Volumes X-XIX, Edited by A. H. Blatt, John Wiley & Sons Publisher, © 1943, pages 10-13.
		Organic Synthesis, Collective Volume 3, being a Revised Edition of Annual Volumes 20-29, E.C. Horning, Editor in Chief, John Wiley & Sons Publishers, © 1955, pages 660-663; ISBN 047 409537.
		Papadoyannis et al, "Solid-Phase Extraction Study and RP-HPLC ...", Journal of Liquid Chromatography, 18(13), 2593-2609 (1995).
		Sinz et al, "Isolation and Characterization of a Novel ...", Drug Metabolism and Disposition, Vol. 19, No. 1, © 1991 by The American Society for Pharmacology and Experimental Therapeutics, pages 149-153.
		Doig et al, "Use of Thermospray Liquid Chromatography-mass ...", Journal of Chromatography, 554 (1991) 181-189.
		Cooper et al, "Simultaneous determination of lamotrigine ...", Journal of Chromatography B, 702 (1997) 227-233.
		ICH Harmonised Tripartite Guideline, Impurities in New Drug Substances, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Tables of Contents, pages 1-10, Recommended for Adoption at Step 4 of the ICH Process on March 30, 1995.
		ICH Harmonised Tripartite Guideline, Impurities in New Drug Substances, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Tables of Contents, pages 1-11, Recommended for Adoption at Step 4 of the ICH Process on February 7, 2002.
		Rote List 1998, Rote List GmbH, December 1997.
		Analysis conducted by Agrobiogen on lamotrigine tablets. Annexure – I, Lamotrigine Impurity Profiling by LC-MS and HPLC; 2003.
		European Council Directive Directive 75/318/ECC of May 20, 1975.

*Examiner		Date Considered	

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.